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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/061,044 | 01/30/2002 | Brian Robert Walker | 674543-2001.1 | 8989 |

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EXAMINER

BADIO, BARBARA P

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1616 | |

DATE MAILED: 04/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/061,044

Applicant(s)

WALKER ET AL.

Examiner

Barbara P. Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 14-17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other:

Final Office Action on the Merits

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

2. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112

3. The rejections of claims 14 and 15 under 35 USC 112, first and second paragraphs are maintained.

Applicant argues that the term "inhibitor" implies the use of any one of a number of well-known compounds. Therefore, according to applicant (a) at the time of filing, applicant had possession of the use of the class of compounds that inhibit 11 β -HSD1 in the claimed methods and (b) claim terms are clear and definite and (c) there is compliance with the written description requirement. Applicant's argument was not persuasive for the following reasons.

To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. That is, the present specification must describe the invention with all its claimed

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limitations, not by what makes it obvious. The use of the term "inhibitor" describes that which would make said compounds obvious. It does not describe the invention with all of its claimed limitations and, thus, does not satisfy the written-description requirement. It is also noted that there is no correlation between a specific structure and claimed inhibitor that would be known by the skilled artisan and the present specification does not provide said correlation.

Again, it is noted that the use of the term "inhibitor" does no more than describe the desired function of the compounds called for but contains no information by which a person of ordinary skill in the art would understand that applicants possessed any other compound, apart from that disclosed in the present specification, having the desired function. Therefore, in order to practice the claimed invention, the skilled artisan would first have to determine compounds having the claimed function. The lack of guidance provided by the present specification to enable the skilled artisan to practice the claimed invention would result in undue experimentation.

For these reasons and those given in Paper No. 5, the rejections¹⁴ and ¹⁵ under 35 USC 112, first and second paragraphs are maintained.

Claim Rejections - 35 USC § 102/103

4. The rejections of claims 14-17 under 35 USC 102(b)/ 103(a) over Stewart et al. are maintained.

Applicant argues the rejections are inconsistent with each other showing that the rejection under 35 USC 102 is erroneous. Applicant also argues the reference does not

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teach or suggest (a) inhibition of 11 β -HSD1 in adipose tissue or the inhibition of the reductase activity of 11 β -HSD1 in adipose tissue and (b) reducing intracellular glucocorticoid concentration in adipose tissue in an animal by inhibiting the reductase activity of 11 β -HSD1 in adipose tissue. Lastly, applicant argues that the art did not recognize that the 11 β -HSD1 is a reductase in adipose tissue. Applicant's argument was considered but not persuasive for the following reasons.

The rejection under 35 USC 102(b) is based on the inherent effect of the administration of carbenoxolone in the treatment of peptic ulcer. That is, the skilled artisan would expect said compound to inhibit 11 β -HSD1 irrespective of the site of the enzyme and, thus, would expect the inhibition of said enzyme in adipose tissue in said patients.

The rejection under 35 USC 103(a) is based on the lack of specific reference by the cited prior art to the inhibition of 11 β -HSD1 in adipose tissue. However, as stated in the previous Office Action, one having ordinary skill in the art at the time of the invention would have the reasonable expectation that the prior art compound/composition would inhibit 11 β -HSD1 irrespective of the cite of said enzyme. The discovery by applicant of a previously unappreciated property of a prior art compound/composition or of a scientific explanation for the prior art's functioning does not lend patentability to a known use of said compound/composition.

For these reasons and those given in Paper No. 5, the rejections of claims 14-17 under 35 USC 102(b)/ 103(a) over Stewart et al. are maintained.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

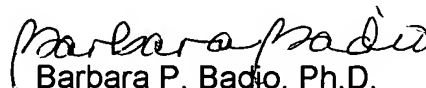
Telephone Inquiry

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Barbara P. Badio, Ph.D.

Primary Examiner

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BB

April 22, 2003